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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,237	01/22/2004	Albrecht Wendel	P61750US1	2027

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,237	WENDEL ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2008 has been entered.

Amendment Entry

2. The amendment filed June 3, 2008 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-22 have been cancelled. New claims 23-34 have been added. Claims 23-34 are under consideration in this office action.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments:

a) The rejection of claims 19-22 under 35 U.S.C. 112, second paragraph,

b) The rejection of claims 19-22 under 35 U.S.C. 102(b) as being anticipated by Rubinstein et al., (PNAS, 1995. Vol. 92, pages 10119-10122); and

c) The rejection of claims 19-22 under 35 U.S.C. 102(b) as being anticipated by Kaye et al., (J. of Virological Methods, 1991. Vol. 35,pages 217-226).

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 23 is unclear. The claim recites selecting a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample, however it is unclear how selecting a cryopreservative relates to determining whether the unit dose reacts with the substance. Therefore clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Livesey et al., (US Patent 5,364,756 published Nov. 15, 1994).

Claim 23 is drawn to a method for testing blood for reaction to a substance comprising the steps of: - selecting a cryopreserved unit dose of a blood product and a

cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal;
- thawing the cryopreserved unit dose; - contacting the thawed, cryopreserved unit dose with the substance; and - determining, by biological, physical, chemical, or physioohemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction. Claim 24 is drawn to the blood product comprising leukocytes. Claim 25 is the blood product comprising whole blood. Claims 26-28 are drawn to the blood product further comprising clotting inhibitors. Claims 29-34 are drawn to the blood product further comprising diluents.

Livesey et al., teach methods for cryopreserving by preparing a cryosolution which includes a buffer, one or more cryoprotectants and a suspension of biological material (col. 3, lines 51-56). Livesey et al., teach the preservation of red blood cells, platelets, leukocytes, Factor VIII, marrow cells, and other material (col. 4, lines 57-64). Livesey et al., teach human erythrocytes are freshly obtained from donors, collected in anticoagulant or erythrocytes are processed from standard blood bank supplies (col. 7, lines 63-68). Example 4 teach the preservation and storage of human erythrocytes. Example 4 teach thawing the erythrocytes where a rehydration substance was added, either adsol buffer, or dextran in buffer and then the erythrocyte samples were then assessed for morphology using phase contrast microscopy.

Therefore Livesey et al., teach the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al., (US Patent 4,731,330 published March 15, 1988) in view of Livesey et al., (US Patent 5,364,756 published Nov. 15, 1994).

Claim 23 is drawn to a method for testing blood for reaction to a substance comprising the steps of: - selecting a cryopreserved unit dose of a blood product and a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal; - thawing the cryopreserved unit dose; - contacting the thawed, cryopreserved unit dose with the substance; and - determining, by biological, physical, chemical, or physioohemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction. Claim 24 is drawn to the blood product comprising leukocytes. Claim 25 is the blood product comprising whole blood. Claims 26-28 are drawn to the blood product further comprising clotting inhibitors. Claims 29-34 are drawn to the blood product further comprising diluents.

Hill et al., teach the preparation and use of whole blood samples for use in other assays in which whole blood control samples are advantageous (col. 2, lines 17-23).

Hill et al., teach whole blood samples comprising lyophilized mixtures or heparinized plasma samples which prevent coagulation (col. 2, lines 48-56). The sample is prepared from either human or non-human mammalian blood (col. 3, lines 10-12). Hill et al., teach other diluting substances (col. 3, lines 25-45). Hill et al., teach freezing the blood to prevent deterioration (col. 4, lines 10-15). Hill et al. teach convenient means for quick-freezing the samples are lyophilized to maintain maximum stability (col. 5, lines 31-35). Hill et al., teach freezing the samples by subjecting them to low temperatures (col. 7, lines 23-26).Hill et al., specifically teach using the samples as a control within a prothrombin time test (col. 5, lines 47-50). The sample is reacted with reagents to produce a detectable signal thereby teaching a immunofunctional or modulatory blood reaction (col. 5, lines 50-68). Hill et al., also teach the control samples being modified to contain other analyte; analyzing the blood samples; and measuring any variation wherein the analyte was added earlier within the process (col. 6, lines 25-35). However, Hill et al., do not teach cryopreserving the units of blood.

Livesey et al., teach the desire to preserve biological material at conditions making them useable for future use is well known (col. 1, lines 30-33). Livesey et al., teach the field of cryopreservation and stabilization wherein the sample is treated with a cryopreservative while preventing irreversible damage due to the multiplicity of changes that occur during cooling and preserving the condition of the sample following cooling (col. 2, lines 25-40). Livesey et al., teach advancements in cryopreservation with overt disruption or destruction of the morphological characteristics of the ultrastructure of the sample (col. 3, lines 22-26).

Therefore it would have been prima facie obvious to modify the method for testing blood for reaction to a substance comprising the steps of: - selecting a frozen unit dose of a blood product and from among a plurality of identical unit doses obtained from a single or pooled sample of blood taken from a human or animal; - thawing the frozen unit dose; - contacting the thawed unit dose with the substance; and - determining, by biological, physical, chemical, or physiochemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction as taught by Hill et al., wherein the modification incorporates the cryopreservation techniques as taught by Livesy et al., in order to provide a cryopreserved unit which prevents irreversible damage due to the multiplicity of changes that occur during cooling and quick-freezing. No more than routine skill would have been required at the time of applicants invention to incorporate well known cryopreservation techniques and cryopreservatives into the method of Hill et al., with no change in their respective functions, especially when the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, the claim would have been obvious because the substitution of quick-freezing for cryopreservation would have yielded predictable results to one of ordinary skill in the art at the time of the invention while preserving the condition of the thawed sample; and one of ordinary skill in the art would have a reasonable expectation of success by exchanging the freezing techniques because the art advantageously teaches the benefits of cryopreservation over freezing as preventing disruption or destruction of the morphological characteristics of the ultrastructure of the sample.

Conclusion

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645